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SEP 12 2011

**510(k) Summary**

**1. Applicant's Name and Address**

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext 25135
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Senior Regulatory Affairs Specialist

**2. Date of Submission:** June 17, 2011

**3. Name of the Device**

Trade Name: Straumann® TiBrush
Common Name: Rotary Scaler
Classification Name: Scaler, Rotary
Regulation Number: §872.4840

**4. Legally Marketed Device to which Equivalence is Claimed (Predicate Device)**

- Curette: operative, periodontic, surgical, Class I, Exempt under 21 CFR §872.4565
- Rotary Scaler, Class II, 21 CFR §872.4840, 510(k) K782007
- EMS Air-flow Master, Class II, 21 CFR §872. 4200, 510(k) K082791

**5. Description of the Device**

The Straumann® TiBrush is made of Grade 5 Titanium and stainless steel for single patient use and is attached to a dental handpiece. It is used during open flap surgery to remove biofilms (plaque and calculus) from the surfaces of dental implants where the surface of the implant is exposed due to peri-implantitis. The TiBrush mechanically removes the biofilms from the surface of the implants without damaging the integrity of the roughened implant surface.

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## 6. Intended Use of the Device

Straumann® TiBrush is a debridement instrument for titanium dental implants subjected to peri-implantitis. It is indicated for the open debridement of titanium implant surfaces in bone defects caused by peri-implantitis. The intended use of the Straumann® TiBrush is equivalent to the currently marketed rotary scaler, EMS Air-Flow Master and curette which are used on the roots of natural teeth whereas the Straumann® TiBrush is for use on the surfaces of dental implants. Endosseous implants have long been considered equivalent to the natural tooth root.

## 7. Technological Characteristics

The Straumann® TiBrush is a brush-like device attached to an oscillating dental handpiece for the removal of biofilms on the surface of dental implants subjected to peri-implantitis. Biofilm is an aggregate of microorganisms in which cells from microorganisms adhere to each other and/or to an implanted surface. These microorganisms are embedded within a self produced matrix of extracellular matrix (ECM). The formation of a biofilm begins with the attachment of free-floating microorganisms to a surface.

Dental plaque (subgingival plaque) is a biofilm which develops naturally on the teeth. The film is soft enough to be removed by a tooth brush. If it is not removed it starts to harden within 48 hours; in about 10 days the plaque starts to mineralize and forms a dental calculus, which is difficult to remove by ordinary dental hygiene methods, like brushing and flossing. The proposed device mechanically removes these contaminants from the surface of the implants without damaging the integrity of the roughened implant surface.

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The patient contacting portion of the Straumann® TiBrush is the titanium bristles; and contact to the patient is less than one hour.

Curettes, rotary scalers and other dental hand pieces using air or water under pressure have traditionally been used for root planning and debridement of natural tooth roots. Comparatively the surface of dental implants is not smooth like the natural tooth; but consists of screw-like threads and a sand blasted, acid etched roughened surface. The hard, inflexible design of a curette, for example, is limited in its ability to access the recesses of the surface without marring and flattening it compared to the flexible bristle design of the Straumann® TiBrush. The titanium bristles of the TiBrush are stiff in order to remove hardened biofilms and have the length, flexibility to be manipulated around the thread design with limited damage to the implant.

The technological characteristic of the TiBrush is different from the curette and water or air dental cleaning hand pieces, but these technological differences result in similar performance as the TiBrush. The TiBrush contains bristles and uses mechanical force. The bristles are better designed to clean implant surfaces and therefore are comparable to the cleaning characteristics of the curved edge of the curette or water or air under pressure.

## 8. Performance Testing

Verification and validation testing were performed to ensure that the Straumann® TiBrush functions as intended and that design input matches design output. Testing included:

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A. Performance Testing

| Test | Description | Results |
|---|---|---|
| Bristle wear during cleaning | Free bristle length >0.40 mm after implant cleaning | passed |
| Damage to implant surface | Sand blasted, acid etched surface cleaned by TiBrush scratch the surface less than the stainless steel curette | passed |
| Corrosion testing | No corrosion | passed |
| Cleaning of implant surface | Removes more plaque than currette | passed |
| Performance at different speeds; 600, 900, 1200, and 3000 rpm | No difference in performance | passed |

B. Biocompatibility testing was conducted in accordance with ISO 10993, various parts. The Straumann® TiBrush met the requirements of the standard.

C. Sterilization validation was conducted in accordance with ISO 11137; requirements of the standard were met.

## 9. Conclusion

The results from the testing conducted demonstrated that the Straumann® TiBrush functions as intended and met pre-determined acceptance criteria. Performance and bench testing indicate that the Straumann® TiBrush is as safe and effective, and performs better than stainless steel curette.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Elaine Alan
Senior Regulatory Affairs Specialist
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

SEP 12 2011

Re: K111724
Trade/Device Name: Straumann® TiBrush
Regulation Number: 21 CFR 872.4840
Regulation Name: Rotary Scaler
Regulatory Class: II
Product Code: ELB
Dated: August 15, 2011
Received: August 16, 2011

Dear Ms. Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known):

Device Name:

Indications for Use:

Straumann® TiBrush is a debridement instrument for titanium dental implants subjected to peri-implantitis. It is indicated for the open debridement of titanium implant surfaces in bone defects caused by peri-implantitis.

Prescription Use X AND/OR Over-the-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of DCRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111724